Newborn Screening Quality Assurance Program

Quality Control Specimen Certification
Galactose-1-Phosphate Uridyltransferase
Set 2
July 13, 2015

GALT ENZYME ACTIVITY LEVELS

Analyte	Lot	Lot	Lot	Expiration Date
Galactose-1-phosphate Uridyltransferase (GALT) (U/g Hb)	1531 Low	1532 Intermediate	1533 High	March 31, 2016

ANALYTICAL INFORMATION

Analyte	Lot	Mean/ 95% CL	Lot	Mean/ 95% CL	Lot	Mean/ 95% CL	Expiration Date
GALT (U/g Hb)	1531	$\bar{x} = 1.4$ CL = 1.1 – 1.8	1532	$\bar{x} = 3.4$ CL = 2.8 – 4.0	1533	$\bar{x} = 7.7$ CL = 6.2 – 9.1	March 31, 2016

Note: The values provided in the above tables are for reference use only. The mean value and confidence limits (CL) are determined by CDC for each Quality Control (QC) lot. Each participating laboratory must establish its own mean values and CL for its test method with these QC materials. Temporary estimates of mean values and CL can be determined after 10 successive, independent measurements.

Reference: *Slazyk WE, Hannon WH. Quality Assurance in the newborn screening laboratory. In: Therrell BL Jr, editor. Laboratory methods for neonatal screening. Washington (DC): American Public Health Association, 1993:23-46.*

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Set 2
July 13, 2015

Previous Lot Transition Materials (parallel testing)

GALT METHOD: PerkinElmer Neonatal GALT Kit

GALT ENZYME ACTIVITY LEVELS

Analyte	Lot	Lot	Lot	Expiration Date
Galactose-1-phosphate Uridyltransferase (GALT) (U/g Hb)	1431 Low	1432 Intermediate	1433 High	August 31, 2015

ANALYTICAL INFORMATION

Analyte	Lot	Mean/ 95% CL	Lot	Mean/ 95% CL	Lot	Mean/ 95% CL	Expiration Date
GALT (U/g Hb)	1431	$\bar{x} = 1.3$ CL = 0.8 – 1.8	1432	$\bar{x} = 4.1$ CL = 3.3 – 5.0	1433	$\bar{x} = 9.5$ CL = 7.8 – 11.1	August 31, 2015

Note: The values provided in the above tables are for reference use only. The mean value and confidence limits (CL) are determined by CDC for each Quality Control (QC) lot. Each participating laboratory must establish its own mean values and CL for its test method with these QC materials. Temporary estimates of mean values and CL can be determined after 10 successive, independent measurements.

Reference: *Slazyk WE, Hannon WH. Quality Assurance in the newborn screening laboratory. In: Therrell BL Jr, editor. Laboratory methods for neonatal screening. Washington (DC): American Public Health Association, 1993:23-46.*